

IMIGRAN™

MIGRAINE RELIEF 50mg film-coated tablets sumatriptan

Package leaflet: Information for the user

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Read this leaflet carefully before taking these tablets.

Remember this medicine is for you. Never give the tablets to someone else, because it may harm them, even if their symptoms seem to be the same as yours.

Keep this leaflet – you may need to read it again. It contains important information. If you have any further questions or there is anything you do not understand, ask your doctor or pharmacist. Throughout this leaflet, Imigran Migraine Relief 50mg film-coated tablets are referred to as Imigran Migraine Relief.

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1 What these tablets do

Imigran Migraine Relief is used to treat migraine. These tablets contain sumatriptan, which belongs to a group of medicines called triptans (*5-HT¹ receptor agonists*). Migraine symptoms may be caused by the temporary swelling of blood vessels in the head due to a temporary imbalance in the body's natural chemicals. The tablets are believed to work on this imbalance and reduce the swelling of these blood vessels. The tablets help to take away the headache and other symptoms of a migraine attack such as feeling sick (nausea) and sensitivity to light and sound. Imigran Migraine Relief is also used for menstrual migraines. They start to relieve migraine headache about 30 minutes after you take them.

2 Check before you take...

Don't take Imigran Migraine Relief:

- **unless you suffer from migraines** (a doctor needs to confirm this)
- **if you are trying to prevent a migraine attack** – only take it when your migraine headache begins
- **until you are sure this is a migraine** and not just a headache
- **if you are under 18 or over 65**
- **if you have had an allergic reaction** to sumatriptan, or any of the other ingredients in the tablets, or to sulphonamide antibiotics
- **if you have heart problems** including heart failure, a previous heart attack, angina (chest pains), or an irregular heart beat
- **if you have had a stroke** or a mini-stroke (*also called a transient ischaemic attack or TIA*)
- **if you have high blood pressure or are being treated for it**
- **if you have kidney or liver disease**
- **if you have epilepsy** or are prone to seizures (fits)
- **if you have circulation problems** in your legs and have cramp-like pains in your legs when you walk, or if your doctor has told you that you suffer from peripheral vascular disease
- **if your doctor diagnosed one of the rare forms of migraine** (hemiplegic, basilar or ophthalmoplegic migraine).

Don't take Imigran Migraine Relief with these medicines:

- **antidepressants called monoamine oxidase inhibitors (MAOIs)**, for example, phenelzine, isocarboxazid, tranylcypromine. If you take these or if you have taken them in the last two weeks, don't take Imigran Migraine Relief. (If you are taking antidepressants and are not sure what they are, talk to your doctor or pharmacist.)
- **certain other migraine treatments to treat the same attack.** Don't take any medicines containing a triptan (including other sumatriptan-containing products, zolmitriptan, rizatriptan, naratriptan) or any medicines containing ergotamine or methysergide with Imigran Migraine Relief.
- any medicines for your migraine which contain ergotamine or ergotamine derivatives, such as ergotamine tartrate or methysergide maleate (if so, you should stop taking them at least 24 hours before taking Imigran Migraine Relief).

Take special care with Imigran Migraine Relief:

- if you have been told that you may have an increased risk of heart disease. You may be considered to have an increased risk of heart disease if you are a man over 40, or a woman who has had the menopause, if you are overweight, a regular smoker, have diabetes, high cholesterol and/or have a close relative who developed early heart disease.
- if your headaches usually last longer than 24 hours, or become more frequent
- if you do not recover completely in between your migraine attacks
- if you are over 50 and this is your first headache of this type
- if your migraine attacks get worse or become more frequent, or your symptoms change
- if your migraine includes symptoms such as
 - weakness on one side of your body – double vision
 - clumsy and un-coordinated movements – tinnitus (ringing in the ears)
 - reduced level of consciousness – seizure (fit)-like movements
 - a recent rash with a headache.

If any of the points in this list apply to you, and you haven't already talked to a pharmacist or doctor about these, get their advice before taking Imigran Migraine Relief. Taking a pain reliever for a headache too often or for too long can make it worse.

If you are taking other medicines:

- **Some antidepressants including lithium and some migraine medicines mean you can't take Imigran Migraine Relief.** See above under *"Don't take Imigran Migraine Relief with these medicines."*
- **Antidepressants called SSRIs or SNRIs** (Selective Serotonin Reuptake Inhibitors or Serotonin Noradrenaline Reuptake Inhibitors) - for example citalopram, fluoxetine, paroxetine, fluvoxamine, sertraline, duloxetine and venlafaxine. There have been rare reports of patients suffering from serotonin syndrome when taking SSRIs or SNRIs and this medicine. Using Imigran Migraine Relief with this group of medicines can make some side effects more likely. If you experience uncontrolled twitching or jerking of the muscles, sweating, and/ or changes in mental status such as confusion or agitation after using Imigran Migraine Relief, tell a doctor straight away. If you are not sure if you are taking an SSRI or SNRI, check with your doctor or pharmacist.
- **Tricyclic antidepressants** – for example doxepin and amitriptyline. Using Imigran Migraine Relief with this group of medicines may make some side effects more likely. If you are worried, talk to your pharmacist or doctor.
- **St John's wort** (a herbal remedy – Hypericum perforatum) – using St John's wort with Imigran Migraine Relief may increase the likelihood of you suffering side effects. If you are worried, talk to your pharmacist or doctor.

Pregnancy and breast-feeding

If you are pregnant or could be pregnant, or you are breast-feeding, **do not take Imigran Migraine Relief unless you've agreed it with your doctor.**

Driving and using machines

Either the symptoms of migraine or your medicine may make you drowsy. **If you are affected, do not drive or operate machinery.**

3 How to take the tablets:

Adults aged 18 to 65

Take your medicine as your doctor has told you. The label on it will usually tell you how many to take and how often. If you are not sure ask your doctor or pharmacist.

The recommended adult dose is one 50mg tablet as soon as the symptoms of your migraine headache appear although they may be taken at any time during a migraine headache attack. Some people may require one 100mg tablet, your doctor will tell you which dose to take.

Don't take more than two tablets in 24 hours.

Don't take more than two tablets for the same attack.

If the first tablet does not provide any relief:

Don't take a second tablet.

Don't take any medicines containing a triptan (including **other** sumatriptan-containing products, zolmitriptan, rizatriptan, naratriptan) or any medicines containing ergotamine or methysergide with Imigran Migraine Relief.

Talk to your doctor before you take any more Imigran Migraine Relief tablets. Getting no relief at all from Imigran Migraine Relief may mean that you do not have migraine.

Imigran Migraine Relief is only to relieve migraine symptoms.

Don't take it to try to prevent an attack. Don't take it until you are sure it's a migraine and not just a headache.

Children under 18 and adults over 65

Do not take this medicine if you are under 18 or over 65 and have migraine symptoms. Talk to your doctor.

What should I do if I take too many tablets?

Taking too much could make you ill. Keep to the dose and follow the instructions. If you take too many tablets, tell a doctor straight away. Take the box and this leaflet with you.

4 Possible side effects

Imigran Migraine Relief can cause side effects, but not everybody gets them.

Allergic reactions: get doctor's help straight away
(affect less than 1 in 10,000 people)

Some people may be allergic to these tablets.

Signs of allergy include rash; wheezing; breathlessness; swollen eyelids, face or lips; complete collapse.

If you get any of these symptoms soon after taking Imigran Migraine Relief, **don't take any more.**

Tell a doctor straight away. Take the packaging and this leaflet with you.

Very rare side effects: tell doctor as soon as possible
(affect less than 1 in 10,000 people)

- Pain in the lower left side of the stomach and bloody diarrhoea.
- Pale, blue-tinged skin and/or pain in your fingers, toes, ears, nose or jaw in response to cold or stress (*Raynaud's phenomenon*).
- Seizures/fits.
- Chest pain or chest tightness.
- Lower abdominal pain and or severe rectal bleeding.
- Visual disturbances such as flickering, reduced vision, double vision and loss of vision (although this is usually transient). These visual disturbances may also be due to the migraine attack itself).
- Uncontrolled movements, shaking or tremors.
- Heart beat may go faster, slower or change rhythm.
- Angina or heart attack.
- Liver function changes, if you have a blood test to check your liver function tell your doctor or nurse that you are taking Imigran Migraine Relief.

Common side effects: tell doctor if long or severe
(affect less than 1 in 10 people)

These effects usually develop within 30 minutes of treatment, and are not usually troublesome. They may be intense, but they do not last long.

- Heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feelings of tingling or warmth.
- Unusual sensations including reduced sensation or numbness and feeling hot/cold.
- Feeling sick (nauseous) or being sick (vomiting) – although this is often part of the migraine attack itself.
- Tiredness or drowsiness.
- Dizziness, feeling weak, or getting hot flushes.
- Feeling faint (blood pressure may go up or down).
- Flushing (redness of the face for a short time).
- Loss of normal colouration in the fingers and toes
- Shortness of breath, difficulty breathing.

If these effects are particularly severe (especially the chest pain), tell your doctor straight away. In a very small number of people, these symptoms can be caused by a heart attack.

If you get any side effects not mentioned above, talk to your doctor or pharmacist.

5 Storing your medicine

Do not store above 30°C. Store in the original package to protect from light. Do not use the tablets after the 'use by end of' date shown on the blister and carton. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Remember: Keep all medicines out of the sight and reach of children.

6 More about the medicine

Active ingredient Each tablet contains 50mg of sumatriptan (as sumatriptan succinate).

Other ingredients of the tablets are anhydrous calcium hydrogen phosphate, microcrystalline cellulose, sodium hydrogen carbonate, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171), triacetin and red iron oxide (E172).

Imigran Migraine Relief packs contain **2, 4, 6, 12, or 18** 50mg tablets. Not all pack sizes may be marketed.

Each film coated tablet is pink, triangular shaped, biconvex and debossed with 'GS 1YM' on one side and '50' on the other.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, CityWest Business Campus, Dublin 24, Ireland. Send all enquiries to this address. The tablets are made by GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland.

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Other sources of Information

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.